

PYXIS REGULATORY CONSULTING, INC.

4110 136th St. NW
Gig Harbor, WA 98332

Phone: 253-853-7369
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www.PyxisRC.com

December 23, 2010

COURIER DELIVERY

Jose Gayoso, Chemical Review Manager
Document Processing Desk (DCI/PRD)
Office of Pesticide Programs (7508P)
One Potomac Yard (South Building)
2777 South Crystal Drive
Arlington, VA 22202

RE: Sulfuryl Fluoride (Chemical No. 078003, Case No. 0176)
Submission of 90-Day Response for Ensystex II, Inc. (EPA Company No. 81824) (ID No. RR-078003-30057)

Dear Mr. Gayoso,

On behalf of Ensystex II, Inc. (EPA Company Number 81824), please find Ensystex's 90-Day response to the Sulfuryl Fluoride Registration Review Generic Data Call-In for Zythor (EPA Reg. No. 81824-1).

In support of this submission, we enclose the following:

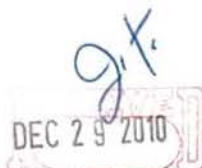
1. Completed Data Call-In Response Form
2. Completed Requirements Status and Registrant's Response Form
3. Copy of the commitment to jointly develop data (Option 2) with Drexel Chemical Company
4. Certification of Attempt to Enter into an Agreement with Registrants for Development of Data
5. Waiver request for certain data requirements
6. Letter of authorization

Please contact me by telephone (253-853-7369) or by e-mail (Janelle@PyxisRC.com) if you have any questions or need any additional information.

Sincerely,


Janelle Kay

Enclosures



United States Environmental Protection
Agency Washington, D.C. 20460

OMB Approval 2070-0174

OMB Approval 2070-0107
OMB Approval 2070-0057

DATA CALL-IN RESPONSE

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form.
Use additional sheet(s) if necessary.

1. Company Name and Address ENSYSTEX II, INC. 4110 136TH ST, NW GIG HARBOR, WA 98332		2. Case # and Name 0176 Sulfuryl Fluoride Chemical # and Name 078003 Sulfuryl fluoride		3. Date and Type of DCI and Number 14-Sep-2010 GENERIC ID # RR-078003-30057	
4. EPA Product Registration	5. I wish to cancel this product regis- tration volun- tarily	6. Generic Data		7. Product Specific Data	
		6a. I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA regis- tration number listed below.	6b. I agree to satisfy Generic Data requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response."	7a. My product is an MUP and I agree to satisfy the MUP requirements on the attached form entitled "Requirements Status and Registrant's Response."	7b. My product is an EUP and I agree to satisfy the EUP requirements on the attached form entitled "Requirements Status and Registrant's Response."
81824-1				N.A.	N.A.
8. Certification I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law. Signature and Title of Company's Authorized Representative <u>Paul M. Bryant</u>				9. Date 12/28/10	
10. Name of Company <u>Ensystex II, Inc.</u>				11. Phone Number <u>253-853-7309</u>	

December 21, 2010

Jose Gayoso, Chemical review Manager
Risk Management and Implementation Branch 2
Pesticide Re-Evaluation Division (7508P)
Office of Pesticide Programs
2777 South Crystal Drive
Arlington, VA 22202

Re: Letter documenting agreement to cost share to develop data jointly relating to sulfuryl fluoride (chemical code 078003), generic data call-in (RR-078003-30057)

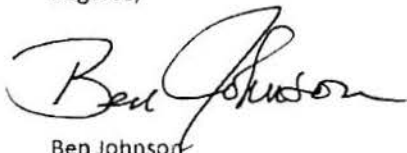
Dear Dr. Gayoso,

Drexel Chemical Company (Drexel) and Ensystex II, Inc. (Ensystex) have received the generic Data Call-In (RR-078003-30057) (DCI) relating to sulfuryl fluoride (chemical code 078003). In accordance with Option 2 of the Generic DCI instructions, this letter provides the Agency with documentation that Ensystex and Drexel have entered into an agreement to jointly develop the following data:

Guideline Number	Guideline Title
875.1400	Inhalation Exposure – Indoor
875.1700	Product Use Information
875.2500	Inhalation Exposure
870.6300	Developmental Neurotoxicity Study
870.7800	Immunotoxicity
SS-2	Avian Inhalation

Please contact Janelle Kay at Janelle@PyxisRC.com or 253-853-7369 if you have any questions about the agreement.

Regards,



Ben Johnson
President
Drexel Chemical Company



Ken Kendall
V.P. Tech Services & Governmental Affairs
Ensystex II, Inc.



United States Environmental Protection Agency
Washington, D.C. 20460

CERTIFICATION OF ATTEMPT TO ENTER INTO AN
AGREEMENT WITH REGISTRANTS FOR
DEVELOPMENT OF DATA

Form Approved.

OMB Nos. 2070-0057;
2070-0107; 2070-0122;
2070-0164

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 15 minutes per response including time for reading the instructions, searching existing data sources, gathering and maintaining the data needed and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, Collection Strategies Division (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Do not send the form to this address.

Please fill in blanks below

Company Name

Ensystex II, Inc.

Company Number

81824

Chemical Name

Sulfuryl Fluoride

EPA Chemical Number

78003

I Certify that:

My company is willing to develop and submit the data required by EPA under the authority of the Federal Insecticide, Rodenticide and Fungicide Act (FIFRA), if necessary. However, my company would prefer to enter into an agreement with one or more registrants to develop jointly or share in the cost of developing data.

My firm has offered in writing to enter into such an agreement. That offer was irrevocable and included an offer to be bound by arbitration under section 3(c)(2)(B)(iii) of FIFRA if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

Name of Firm(s)

Dow AgroSciences, LLC

Date of Offer

Dec. 23, 2010

Certification:

I certify that I am duly authorized to represent the company name above, and that the statements that I have made on this form and all attachments therein are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature of Company's Authorized Representative

Date

12/31/10

Name and Title (Please Print or Type)

Janelle Kay, Agent

**Waiver Requests for Submission of Generic Data for Ensystex II, Inc.
Sulfuryl Fluoride (Case Number 0176, Chemical Code 078003)**

Guideline Number	Guideline Title	Waiver Request Justification
SS-3	Terrestrial Plant Toxicity	<p>The Data Call-In (DCI) requested the submission of plant toxicity data, primarily to assess risks to "endangered and other non-target plants downwind from release points of sulfuryl fluoride." (Problem Formulation). The toxicity of sulfuryl fluoride to plants is commonly known and is not disputed. Ensystex II, Inc. (Ensystex) has worked with sulfuryl fluoride over a number of years and has observed plant toxicity to plants exposed to sulfuryl fluoride under the tarping system used during application.</p> <p>Ensystex understands that the primary purpose of EPA needing these data is to conduct risk assessments to endangered plants and that without these data, "use of sulfuryl fluoride may need to be restricted in areas where endangered species could be exposed." However, based on the nature of the application of sulfuryl fluoride, Ensystex does not expect any Threatened or Endangered species to be at or near the application or aeration points of sulfuryl fluoride. Sulfuryl fluoride is only applied in structures, buildings, vehicles, ships, etc. The land surrounding these structures is managed and not considered habitat for endangered plants. Indeed, most jurisdictions require significant buffers between known locations of Threatened or Endangered plants and structures or land disturbance.</p> <p>Furthermore, and most importantly, sulfuryl fluoride dissipates very rapidly to below detectable limits a short distance away when a structure is aerated. Ensystex intends on demonstrating this to the Agency with the development and submission of the post-application exposure data required with this DCI.</p> <p>Therefore, Ensystex requests that the submission of terrestrial plant toxicity data be reserved until the submission and review of its post-application exposure data. Ensystex is confident that based on the current label warnings, the post-application exposure data and the proximity of Threatened or Endangered plants to applications of sulfuryl fluoride that the Agency will have sufficient information to conduct its risk assessments without the submission of plant toxicity data and will waive the data requirement.</p>
SS-4	Monitoring Data on Fumigated Commodities	<p>Ensystex believes this data requirement is not applicable to its registration and therefore, respectfully requests a waiver for the submission of these data. Ensystex's only sulfuryl fluoride registration, Zythor (EPA Reg. No. 81824-1) is not labeled for use on stored commodities; it is only labeled for use in structures, buildings, vehicles where food commodities have been properly removed or bagged. A copy of the most recent stamped approved label, excluding the applicator's manual, is attached.</p>

ENSYSTEX II, Inc.

2709 Breezewood Ave., P. O. Box 2587, Fayetteville, NC 28302-2587
Telephone - 1-910-484-6163 x 203 Fax - 1-910-484-3378

August 18, 2004

To Whom It May Concern:


Re Letter of Authorization

Dear Sir or Madam:

Please let this letter serve to confirm that Pyxis Regulatory Consulting, Inc. is authorized to act as agent for Ensystex II, Inc. (EPA Company Number pending), before the U.S. Environmental Protection Agency and state governmental agencies in all matters regarding our pesticide registrations pursuant to the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136 et seq. and state law.

If you have any questions, please do not hesitate to contact me.

Sincerely,


David R Nimocks III
President

cc: Pyxis Regulatory Consulting, Inc.

State of North Carolina
County of Cumberland

I, Linda Barber, a Notary Public for said County and State, do hereby certify that David R. Nimocks, III personally appeared before me this day, August 18, 2004 and acknowledged the due execution of the foregoing instrument.



